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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,099	01/10/2001	Michael Laposata	M0765/7034HCL/MAT	7656
7590	09/21/2004		EXAMINER	
Helen C. Lockhart Wolf, Greenfield & Sacks, P.C. Federal Reserve Plaza 600 Atlantic Avenue Boston, MA 02210-2211			COLE, MONIQUE T	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 09/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,099

Applicant(s)

LAPOSATA, MICHAEL

Examiner

Monique T. Cole

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,29,31,35,45,95,117-139 and 176-178 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35,45,95 and 121-139 is/are allowed.
- 6) ☒ Claim(s) 28, 29, 31, 117-120, 176-178 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 176-178 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has added claims 176-178 that recite that two or readouts are determined from the computerized method of claim 95. Applicant has pointed to page 6, the first full paragraph for support of these additional claims. It is not clear where the support is found for these newly added claims. The specification provides for a computer program product with a computer readable medium and computer readable signals that define instructions based on a series of steps that may be performed singly or in combination. However, the specification in the cited passage does not provide support for the claimed readouts. Further clarification and/or cancellation is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 28, 29, 31 & 117-120 rejected under 35 U.S.C. 103(a) as being unpatentable over "Fatty Acid Ethyl Esters: Ethanol Metabolites Which Mediate Ethanol-Induced Organ Damage and Serve As Markers of Ethanol Intake" by Laposata (herein referred to as "Laposata").

Laposata teaches that FAEE's correlate to the incidence of ethanol intake in liver and adipose tissue found in human subjects, particularly in infants and deceased individuals. FAEE's can serve as both a long term and short term marker of ethanol ingestion. FAEE's persist in the test samples for at least 24h after ethanol intake was completed. There is clinical utility for the FAEE measurement, as several algorithms have been developed to monitor ethanol intake.

See page 308, 1st full paragraph; page 313, last full paragraph; page 314, 3rd full paragraph-conclusion of the reference.

Laposata differs from the instantly claimed invention in that its determination of FAEE is not exclusive to liver & adipose tissue samples. However, since the instant claims are open to the inclusion of additional steps (i.e., "comprising" language), the claim would read on a method of determining the total FAEE derived from many sources such as the pancreas, liver, heart, brain and adipose tissue disclosed as sources of FAEE in Laposata. The total FAEE in Laposata would include an addition of the FAEE from all of these sources.

Laposata further differs from the instant claims in that it does not expressly disclose the amount of FAEE that is present in order to make the determination of ethanol intake. However, "it is the normal desire of scientists or artisans to improve upon what is already generally known." MPEP 2144.05.II.A. The Laposata reference makes a determination of heightened ethanol intake. This determination would require a comparison of the measured amount of FAEE in a subject to a known baseline amount of FAEE. It would necessarily follow that in order to diagnose heightened ethanol intake, an elevated range would be ascertained. Thus, it would have been obvious to one having ordinary skill in the art to modify the Laposta reference by selecting any number within the elevated range with the expectation that samples equaling or exceeding that amount would be reliable indicators of ethanol intake.

Response to Arguments

2. Applicant's arguments, see remarks, page 8, filed 7/12/2004, with respect to the rejection(s) of claim(s) 28, 29, 31, 45, 95 & 117-139 under 35 USC 102(b) have been fully

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considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the same reference under 35 USC 103. Applicant's arguments with respect to claims 28, 29, 31 and 117-120 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter


3. Claims 35, 45, 95 & 121-139 are allowed.
4. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest that a ratio of the amount of total liver FAEE to the amount of total adipose FAEE of at least 2 is indicative of ethanol intake; the prior art does not teach or suggest ethyl arachidonate in at least 200 pmol/gram in the tissue, singularly, to indicate ethanol intake.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Monique T. Cole
Examiner
Art Unit 1743

MC